CFSAN201156

4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 172, 173, 178, and 180

[Docket No. FDA-2010-F-0320]

United States Pharmacopeial Convention; Filing of Food Additive Petition; Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is amending the filing notice for a food additive petition filed by the U.S. Pharmacopeial Convention requesting that the food additive regulations that incorporate by reference food-grade specifications from prior editions of the Food Chemicals Codex (FCC) be amended to incorporate by reference food-grade specifications from the FCC, 7th Edition.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Mical E. Honigfort,

Center for Food Safety and Applied Nutrition (HFS-265),

Food and Drug Administration,

5100 Paint Branch Pkwy.,

College Park, MD 20740-3835,

240-402-1278.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register on August 10, 2010 (75 FR 48353), FDA announced that a food additive petition (FAP 0A4782) had been filed by U.S. Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852. The petition proposes that certain food additive regulations, which incorporate by reference food-grade specifications from prior editions of the FCC, be amended to incorporate by reference food-grade specifications from the FCC, 7th Edition.

Under 21 CFR 171.1(c)(H), either a claim of categorical exclusion under § 25.30 (21 CFR 25.30) or 21 CFR 25.32 or an environmental assessment under 21 CFR. 25.40 is required to be submitted in a food additive petition. A claim of categorical exclusion under § 25.30(i) was submitted with the petition, which applies to corrections and technical changes in regulations. The Agency reviewed the claim of categorical exclusion submitted by the petitioner and stated in the original filing notice its determination that, under § 25.30(i), the proposed action was of a type that does not individually or cumulatively have a significant effect on the human environment, and therefore, neither an environmental assessment nor an environmental impact statement is required.

However, upon further review of the petition, the Agency has decided that the actions being requested in the petition are neither corrections nor technical changes, and,

therefore, the categorical exclusion in § 25.30(i) is not applicable for the proposed action. The Agency informed the petitioner of this decision, who subsequently submitted an environmental assessment.

The potential environmental impact of this petition is being reviewed. To encourage public participation consistent with regulation issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see DATES and ADDRESSES) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the Federal Register. If, based on its review, the Agency finds that an environmental impact statement is not required, and this petition results in a regulation, the notice of availability of the Agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.51(b).

Dated: January 6, 2012.

Dennis M. Keefe,

Director,

Office of Food Additive Safety,

Center for Food Safety and Applied Nutrition.

[FR Doc. 2012-797 Filed 01/17/2012 at 8:45 am; Publication Date: 01/18/2012]